THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI SHATRUGHAN SINHA): (a) The details of financial outlays earmarked for National Health Care Programmes during the Ninth Plan, Tenth Plan and Annual Plan 2002-03 are annexed as Statement (*See* below).

(b) to (d) Assistance to States/UTs under the National Health Programmes is provided as per the norms prescribed in each scheme. As per the Government policy, 10% of the Central Sector Health outlay is earmarked for the North Eastern Region including Sikkim. Under the National Leprosy Eradication Programme provission for Special Action Projects for Elimination of Leprosy (SAPEL) and Leprosy Elimination Campaign (LEC) for backward regions has already been made. Under National Anti Malaria Programme, 100% Central assistance is being provided to States of North-Eastern Region as against 50:50 sharing basis in other States. In addition an Enhanced Malaria Control Project (EMCP) with World Bank assistance is also in operation in eight States covering 100 tribal predominant districts.

Statement

The details of financial outlays earmarked for National Health Care Programmes during the Ninth Plan and Annual Plan (2002-03)

Programme	Outlays (Rs. in crore)		
	IX Plan 1997-02	X Plan* 2002-07	Annual Plan 2002-03
Malaria	1030	1370	235
Leprosy	301	255	75
Tuberculosis	450	680	115
AIDS	760	1270	225
Blindness	448	445	86
Cancer	190	285	61
Mental Health	28	190	30

*subject to approval by N.D.C.

Use of discretion in granting permissions for clinical trials

1246. SHRI MUNAVVAR HASAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Drug Controller General of India (DCGI) is using his

discretion in granting permissions for clinical trials, bio-equivalences and marking permissions;

(b) whether it is also a fact that often there are variations in the decisions from company to company;

(c) the procedures laid down for Bio-Tech products;

(d) the details of drugs cleared in 2002, so far; and

(e) the date on which the applications were received alongwith the names of medicines and the time taken to grant permission?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) and (b) No, Sir. Application for permission for clinical trials, bio-equivalence studies and marketing of new drugs are examined by the New Drug division in the office of DCG (I). The requirement for granting such approvals are specified in Rules 122A to 122E and Schedule Y of Drugs and Cosmetics Act and Rules made thereunder.

The evaluation of new drug applications is a complex process as per Schedule-Y under Drugs and Cosmetics rules and varies according to the nature of molecule/drug, published data and information furnished by the applicants. Therefore, depending upon the nature of the application, it may take on an average 3 to 5 years for an applicant to complete all phase of trials required for approval of investigational New Drug (*i.e.* a drug molecule not tested on human being anywhere in the world); about 1—3 years for the first time approval of the drug already approved elsewhere but requiring confirmatory clinical trial, and about 2-3 months for subsequent applications for already approved drugs. This is however, subject to submission of all required data as per provisions of Schedule-Y of Drug and Cosmetics Rules and opinion from experts. Certain critical drugs *e.g.* anti-cancer, anti-HIV, immunosuppresent, etc., which are critical from the point of view of public health are cleared on a fast track basis.

(c) Procedure for approval of new Bio-tech (r-DNA derived therapeutic drugs) products are the same as prescribed under rule 122A to 122E and Schedule Y of Drugs and Cosmetics Rules. However, clearance from RCGM (Review Committee for Gene Manipulation) under DBT is required for indigenously developed bio-tech drug and a general clearance for import and manufacture of all bio-tech products is to be given by GEAC (Genetic Engineering Approval Committee) under Ministry of Environment.

(d) and (e) The details of the drugs cleared during in 2002 is annexed as statement.

Statement

Details of new drugs cleared from 1st January 2002 to 31st October 2002

S.No.	Name of the drug	Name of the firm	Application date	Approval date
1.	Meropenan Inj.	M/s. Astra Zeneca Ltd.,	07-08-2001	08-01-2002
2.	Dimatoprost-Opth.	M/s. Allergan India Ltd.,	28-03-2001	08-01-2002
3.	Fosinopril Sod.	M./s. Cadila Pharma Ltd.,	23-03-2001	10-01-2002
4.	Zaleplon	M/s. Torrent Pharma.,	30-05-2001	17-01-2002
5.	Montelukast Sodium	M/s. Ranbaxy Lab.,	07-11-2000	13-02-2002
6.	DtaP Vaccine	M/s. Aventis Pharma.,	16-07-1997	01-02-2002
7.	Thymogen	M/s. Nicholas Piralmal Ltd.,	15-12-1997	12-02-2002
8.	Mifepristone	M/s. Cadila Healthcare Ltd.,	25-06-1996	13-02-2002
9.	Mecobalamin Inj.	M/s. Wockhardt Ltd.,	03-01-2002	14-02-2002
10.	Dexrazoxen	M/s. A. Sarabhai Ltd.,	27-09-2000	26-02-2002
11.	Bicalutamide	M/s. Cipla Ltd.,	21-05-2001	07-03-2002
12.	Apraclonidene	M/s. Cipla Ltd.,	27-01-1998	15-03-2002
13.	Mizolastine	M/s. Dr. Reddy's Lab Ltd.,	20-07-2001	15-03-2002
14.	Miltefosine	M/s. German Remedies Ltd.,	27-02-2002 (C/T initiated on 12-11-1996)	15-03-2002
15.	Loteprednol	M/s. Sun Pharma Ltd.,	31-07-2001	15-03-2002
16.	Ziprasidone	M/s. Torrent Pharma Ltd.,	09-04-2001	15-03-2002
17.	Tranexamic Acid	M/s. Macleods Pharma Ltd.,	24-04-2002	16-03-2002
18.	Abcavir	M/s. Hetero Drugs Ltd.,	11-06-2001	22-03-2002
19.	Nadifloxacin	M/s. Wockhardt Ltd.	07-12-1998	28-03-2002
20.	Famcyclovir	M/s. Cipla Ltd.,	25-11-2000	11-04-2002
21.	Tamsulosin	M/s. Cipla Ltd.,	20-08-1998	15-04-2002
22.	Nateglinide	M/s. Alembic Ltd.,	05-07-2000	01-05-2002
23.	Larcanidipine	M/s. Sun Pharma Ltd.,	10-01-2002	07-05-2002
24.	Quetiapine	M/s. Sun Pharma Ltd.,	07-11-2001	31-05-2002
25.	Itopride	M/s. Knoll Pharma Ltd.,	27-09-1999	09-05-2002
26.	Alprostradil	M/s. Pharmacia India Ltd.,	10-12-1997	09-05-2002
27.	Isotretinoin	M/s. Cipla Ltd.,	16-01-2000	21-06-2002
28.	Nebivolol	M/s. Sarvotam Care Ltd.,	19-04-2000	12-07-2002
29.	Pygenum A. Extract	M/s. Serum Institute, Pune	20-06-1995	30-07-2002

S.No.	Name of the drug	Name of the firm	Application date	Approval date
30.	Serolimus	M/s. Wyeth Lederle..	09-07-1999	15-07-2002
31.	Drotrecogin alpha	M/s. Eli Lilly Ltd..	27-03-2002	23-07-2002
32.	Valdecoxib	M/s. Glenmark India Ltd..	09-04-2002	01-08-2002
33.	Thalidomide	M/s. Dabur India Ltd..	23-04-2002	12-08-2002
34.	(s)-Amlodipine	M/s. Emcure Pharma Ltd..	26-06-2001	16-08-2002
35.	Cabergoline	M/s. Sun Pharma Ltd..	20-08-2001	05-09-2002
36.	Butorphenol	M/s. Aristo Pharma Ltd..	13-03-2000	11-09-2002
37.	Gemtuzumab	M/s. Wyeth Laderle Ltd..	02-11-2000	12-09-2002
38.	Quinapril	M/s. Macleods Pharma Ltd..	18-07-2001	19-09-2002
39.	Valacyclovir	M/s. Cipla Ltd..	16-09-1998	25-09-2002
40.	Fosphenytoin	M/s. Cadila Healthcare Ltd..	05-11-2001	01-10-2002
41.	Ceftiofur	M/s. Aurobindo Pharma Ltd.	11-02-2002	08-10-2002
42.	Metexalon	M/s. Sun Pharma Ltd..	23-11-2001	08-10-2002
43.	Acamprosate	M/s. Sun Pharma Ltd..	16-07-2001	30-10-2002
44.	Cefepime	M/s. Aurobindo Pharma Ltd..	31-07-2001	30-10-2002

National AIDS Policy

†1247. SHRI BALKAVI BAIRAGI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the main features of National AIDS Policy and the instructions issued for the prevention of increasing HIV infection in the country;

(b) the safety measures taken to protect the children and women of weaker sections of the society from AIDS infection under the said policy; and

(c) the places in backward and tribal areas of Andhra Pradesh where voluntary test facilities of HIV infections are set-up/proposed to be set-up in accordance with the said policy?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) to (c) The salient features of National AIDS Prevention and Control Policy are as under:—

(i) to prevent the epidemic from spreading further and to reduce the impact of the epidemic not only upon the infected persons but upon the health and socio-economic status of the general population at all levels,

†Original notice of the question was recieved in Hindi.